Full Day Short Course

EuroAnalysis Geneva 2023
27-31 August 2023 Switzerland

F01. From method validation to method performance assessment: the benefits of the analytical methods life cycle concept

Content

1 *What is the Analytical Method Life Cycle concept?*

ICH Q14 draft guideline and USP <1220> chapter insights

The analytical method performance assessment steps during method life cycle

2 *Analytical methods robustness: Why and how*

The need for a Method Operable Design Region

Use of Design of Experiments in robustness studies

Using prediction intervals in robustness assessment

3 *Method validation: the "Old" and the "New"*

A 30-year history: the 3 periods of method validation concept

To understand the "New", we must know the "Old":

"You'll be linear, Son!"

True or Accurate?

"New" concepts in calibration function assessment

Calibration functions comparison

"New" concepts in accuracy assessment

Prediction and tolerance intervals

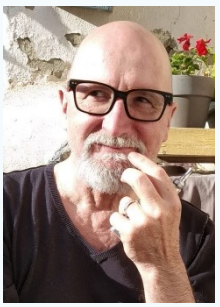
What about uncertainty of measurements?

4 *Analytical methods on-going performance assessment*

Use of control charts for method performance monitoring

Details

Instructors	Dr. Jean-Marc Roussel Prof. Serge Rudaz
Date	27 August 2023
Time	9:00 h – 16:30 h
Duration	2 x 3 h plus lunch
Location	CICG Geneva
Fees	200 CHF (delegate) 120 CHF (student)
Included	Coffee break, lunch



Dr. J.-M. Roussel

Prof. S. Rudaz

Instructors

Dr. Jean-Marc Roussel is an independent consultant who helps industry laboratories to develop and validate analytical methods. His consultancy activity also includes lectures and training related to liquid chromatography, sample preparation and statistics applied to analytical chemistry. He is co-designer of NeoLiCy®, software for analytical method's life cycle statistical assessment. He is chairman of the "Uncertainty of Measurement" and Co-Chairman of the "Analytical Methods Robustness" committees of the French Society for Pharmaceutical Sciences and Techniques.

Dr. Serge Rudaz is Professor at the University of Geneva where he leads the biomedical and metabolomics analysis group. He is interested in UHPLC and CE coupled to MS, advances in sample preparation, analysis of pharmaceuticals and counterfeits medicines, biological matrices, clinical and preclinical studies, including metabolism and toxicological analysis. Serge Rudaz is an expert in a variety of chemometric approaches, including experimental design (DOE) validation and regulation (ISO17025), as well as multivariate data analysis (MVA). His research group has also focused on developing chemometric approaches dedicated to the analysis of data produced by MS couplings.